

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tylan 200, 200 mg/ml Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains 200 mg of Tylosin base activity in 50% propylene glycol with 4% benzyl alcohol.
Tylosin 200 mg/ml

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle and pigs

6. INDICATION(S)

FOR INTRAMUSCULAR USE IN CATTLE AND PIGS

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage and Administration

Inject intramuscularly only. A dry hypodermic needle and syringe should be used where possible. It is advisable to alternate the injection site when repeated daily doses are given.

Cattle and calves: 4 to 10 mg. per kg body weight (1 ml per 20 - 50 kg) daily.

The maximum injection volume for cattle is limited to 15 ml per injection site.

Pigs: 2 to 10 mg. per kg body weight (1 ml per 20 – 100 kg) daily.

In pigs, doses may need to be divided evenly between injection sites. In pigs do not administer more than 5 ml per injection site. To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing. See enclosed leaflet.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):

Pigs: Meat and offal – 16 days

Cattle: Meat – 28 days
Milk – 108 hours

With cows milked twice daily, milk for human consumption may be taken only from 108 hours (i.e. at the 9th milking) after the last treatment. With other dosing routines, the basis of the veterinary surgeons advice should be that milk may be taken for human consumption only after the same period from the last treatment (i.e. with three times a day milking, milk for human consumption may be taken only from 108 hours (i.e. at the 14th milking).

9. SPECIAL WARNING(S), IF NECESSARY

User Warnings

Avoid accidental self-injection and any contact with skin and eyes. Wash off any splashes immediately with clean running water. Seek medical attention if irritation persists. Wash hands after use.

Blemishes may occur at the site of injection and can persist for up to 21 days following administration.

Tylan 200 should not be given to chickens or turkeys.

Do not administer to horses or other equines.

Injection of Tylosin in equines has been fatal.

10. EXPIRY DATE

Use Before:

Date of broaching:

Date to discard:

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton.

Do not store above 25° C.

Following withdrawal of the first dose use the product within 28 days.

Discard unused material.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with national requirements.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

FOR ANIMAL TREATMENT ONLY.

TO BE SUPPLIED ONLY ON VETERINARY PRESCRIPTION.

POM-V

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4204

17. MANUFACTURER’S BATCH NUMBER

Lot No.:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100ml VIAL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tylan 200, 200 mg/ml Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Tylosin 200 mg/ml

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle and pigs

6. INDICATION(S)

FOR INTRAMUSCULAR USE IN CATTLE AND PIGS

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage and Administration

Inject intramuscularly only. A dry hypodermic needle and syringe should be used where possible. It is advisable to alternate the injection site when repeated daily doses are given.

Cattle and calves: 4 to 10 mg. per kg body weight (1 ml per 20 - 50 kg) daily.

The maximum injection volume for cattle is limited to 15 ml per injection site.

Pigs: 2 to 10 mg. per kg body weight (1 ml per 20 – 100 kg) daily.

In pigs, doses may need to be divided evenly between injection sites. In pigs do not administer more than 5 ml per injection site. To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing. See enclosed leaflet.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):

Pigs: Meat and offal – 16 days.

Cattle: Meat – 28 days

Milk – 108 hours

With cows milked twice daily, milk for human consumption may be taken only from 108 hours (i.e. at the 9th milking) after the last treatment. With other dosing routines, the basis of the veterinary surgeons advice should be that milk may be taken for human consumption only after the same period from the last treatment (i.e. with three times a day milking, milk for human consumption may be taken only from 108 hours (i.e. at the 14th milking).

9. SPECIAL WARNING(S), IF NECESSARY

User Warnings

Avoid accidental self-injection and any contact with skin and eyes. Wash off any splashes immediately with clean running water. Seek medical attention if irritation persists. Wash hands after use.

Blemishes may occur at the site of injection and can persist for up to 21 days following administration.

Tylan 200 should not be given to chickens or turkeys.

Do not administer to horses or other equines.

Injection of Tylosin in equines has been fatal.

10. EXPIRY DATE

Date of broaching:

Date to discard:

Use Before:

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton.

Do not store above 25° C.

Following withdrawal of the first dose use the product within 28 days.

Discard unused material.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with national requirements.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

FOR ANIMAL TREATMENT ONLY.

TO BE SUPPLIED ONLY ON VETERINARY PRESCRIPTION.

POM-V

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4204

17. MANUFACTURER'S BATCH NUMBER

Lot No.:

B. PACKAGE LEAFLET

**PACKAGE LEAFLET:
Tylan 200, 200 mg/ml Solution for Injection**

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER
AND OF THE MANUFACTURING AUTHORISATION HOLDER
RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder:

Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

Manufacturers responsible for batch release:

Elanco UK AH Limited
Elanco Speke Operations,
Fleming Road,
Speke,
Liverpool,
L24 9LN,
United Kingdom

Elanco France S.A.S.
26 Rue de la Chapelle
68330 Huningue
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tylan 200, 200 mg/ml Solution for Injection

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER
INGREDIENT(S)**

Tylosin 200 mg/ml

Tylosin is an antibiotic fermentation product of a soil isolate closely resembling *Streptomyces fradiae*, which was isolated in the Lilly Research Laboratories from a soil sample collected in Thailand.

Presentation

A sterile yellow aqueous solution of tylosin base in 50% propylene glycol with 4% benzyl alcohol. Each ml contains 200 mg of tylosin activity (as tylosin base).

4. INDICATION(S)

FOR INTRAMUSCULAR USE IN CATTLE AND PIGS

Recommended for the treatment of large animals.

Properties

Tylan 200 possesses a wide spectrum of antibiotic activity against micro-organisms.

Particularly active against Gram-positive bacteria, it is also effective against several species of spirochaetes, Chlamydia and certain Gram-negative bacteria. Tylan 200 is indicated in all conditions associated with bacteria sensitive to tylosin which includes organisms in the following genera:

<i>Streptococcus</i>	<i>Campylobacter</i>	<i>Fusiformis</i>
<i>Bacillus</i>	<i>Spirochaetes</i>	
<i>Staphylococcus</i>	<i>Corynebacterium</i>	
<i>Clostridium</i>	<i>Pasteurella</i>	
<i>Erysiplothrix</i>	<i>Chlamydia</i>	

Tylan 200 has been successfully used in respiratory and genito-urinary tract infections, otitis, cellulitis and secondary bacterial conditions associated with virus disease or post operative infections.

Specific disease entities treated successfully with Tylan 200 include: Swine Dysentery, Erysipelas and Enzootic Pneumonia in pigs, foul in the foot, mastitis and calf pneumonia in cattle. In general, Tylan 200 can be successfully used in the treatment of conditions associated with, or caused by bacteria sensitive to tylosin. Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local epidemiological information.

5. CONTRAINDICATIONS

Contra-indications

For animal treatment only.

Do not administer to chickens or turkeys.

Do not administer to horses or other equines. Injection of Tylosin in equines has been fatal.

6. ADVERSE REACTIONS

Adverse Reactions

Possible adverse reactions attributed to the product when used as recommended and their frequency are: In very rare cases the following have been observed;

- swelling/inflammation at the site of injection,
- vulvular swelling in cattle,
- oedema of the rectal mucosa, partial anal protrusion ('rosebudding'), erythema and pruritus in pigs,
- anaphylactic shock and death.

As with the injection of any foreign substance, a reaction may occur in animals. Since temporary irritation may occur at the site of injection in swine, it is suggested that a sufficient time interval be allowed before animals are slaughtered for food. To avoid blemish at point of injection, do not slaughter pigs within 21 days of administration.

7. TARGET SPECIES

Cattle and pigs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage and Administration

Inject intramuscularly only. A dry hypodermic needle and syringe should be used where possible. It is advisable to alternate the injection site when repeated daily doses are given.

Cattle and calves: 4 to 10 mg. per kg body weight (1 ml per 20 - 50 kg) daily.

The maximum injection volume for cattle is limited to 15 ml per injection site.

Pigs: 2 to 10 mg. per kg body weight (1 ml per 20 – 100 kg) daily.

In pigs, doses may need to be divided evenly between injection sites. In pigs do not administer more than 5 ml per injection site. To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

Caution

The administration of antibiotics may result in the over-growth of non-susceptible organisms.

If new infections due to bacteria or fungi appear during treatment with this drug, appropriate measures should be taken. If there is no response to therapy in 3 days, diagnosis and treatment should be reassessed.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

PIGS: Meat and offal – 16 days

CATTLE: Meat – 28 days

Milk – 108 hours

With cows milked twice daily, milk for human consumption may be taken only from 108 hours (i.e. at the 9th milking) after the last treatment. With other dosing routines, the basis of the veterinary surgeons advice should be that milk may be taken for human consumption only after the same period from the last treatment (i.e. with three times a day milking, milk for human consumption may be taken only from 108 hours (i.e. at the 14th milking).

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Keep out of the reach and sight of children.

Following withdrawal of the first dose use the product within 28 days. Discard unused material. When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

12. SPECIAL WARNING(S)

User Warnings

Avoid accidental self-injection and any contact with skin and eyes. Wash off any splashes immediately with clean running water. Seek medical attention if irritation persists. Wash hands after use.

Interaction with other medicinal products and other forms of interaction:

Do not mix Tylan 200 mg/ml Solution for Injection with other solutions, as this may cause a precipitation of the active ingredient.

Special precautions for use in animals:

The efficacy data do not support the use of tylosin for the treatment of bovine mastitis caused by *Mycoplasma* spp.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Disposal

Dispose of any unused product and empty containers in accordance with national requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

February 2021

15. OTHER INFORMATION

POM-V

TO BE SUPPLIED ONLY ON VETERINARY PRESCRIPTION

Tylan 200 is relatively non-toxic. The oral LD₅₀ in mice is greater than 5 g per kg. Dogs have tolerated oral doses as high as 200 mg and 400 mg/kg for 657 days with only occasional side-effects, for example, vomiting and salivation. Overdoses of this nature have resulted in an occasional animal showing haematuria for several days. This was only evident some time after 20 to 190 days after administration. In pigs, the LD₅₀ by the intramuscular route is approximately 1 g per kg and by the oral route, greater than 5g per kg. Blood level studies have been conducted in cattle and pigs comparing Tylan 200 for injection to aqueous solutions of tylosin tartrate. A longer duration of activity was evinced with Tylan 200 for injection. Measurable blood levels of 22 hours duration can be expected in cattle with a single injection of the preparation at recommended doses. There has been no evidence of undue irritation in cattle at the site of injection. These studies, plus others in rats, chickens, pigs, cattle and calves further demonstrate the relative safety of this substance.

Vm 00879/4204

Revised: February 2021
AN: 01593/2020

Tylan 200 is supplied in multidose colourless glass bottles containing 50 ml, 100 ml or 250 ml.
Not all pack sizes may be marketed.

Approved: 18/02/21

A handwritten signature in black ink that reads "D. Austin". The signature is written in a cursive style with a horizontal line extending from the end.